

§ 153.620

and accurate risk adjustment data in the manner and timeframe established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

(d) *Assessment of charges.* An issuer that offers risk adjustment covered plans that has a net balance of risk adjustment charges payable, including adjustments made pursuant to §153.350(c), will be notified by the State, or by HHS on behalf of the State, of those net charges, and must remit those risk adjustment charges to the State, or to HHS on behalf of the State, as applicable.

(e) *Charge submission deadline.* An issuer must remit net charges to the State, or HHS on behalf of the State, within 30 days of notification of net charges payable by the State, or HHS on behalf of the State.

(f) *Assessment and collection of user fees for HHS risk adjustment operations.* Where HHS is operating risk adjustment on behalf of a State, an issuer of a risk adjustment covered plan (other than a student health plan or a plan not subject to 45 CFR 147.102, 147.104, 147.106, 156.80, and subpart B of part 156) must, for each benefit year—

(1) Submit or make accessible to HHS its monthly enrollment for the risk adjustment covered plan for the benefit year through the risk adjustment data collection approach established at §153.610(a), in a manner and timeframe specified by HHS; and

(2) Remit to HHS an amount equal to the product of its monthly enrollment in the risk adjustment covered plan multiplied by the per-enrollee-per-month risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

[77 FR 17248, Mar. 23, 2012, as amended at 78 FR 15531, Mar. 11, 2013]

§ 153.620 Compliance with risk adjustment standards.

(a) *Issuer support of data validation.* An issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State.

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjust-

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ment covered plans must retain any information requested to support risk adjustment data validation for a period of at least ten years after the date of the report.

§ 153.630 Data validation requirements when HHS operates risk adjustment.

(a) *General requirement.* An issuer of a risk adjustment covered plan in a State where HHS is operating risk adjustment on behalf of the State for the applicable benefit year must have an initial and second validation audit performed on its risk adjustment data as described in this section.

(b) *Initial validation audit.* (1) An issuer of a risk adjustment covered plan must engage one or more independent auditors to perform an initial validation audit of a sample of its risk adjustment data selected by HHS.

(2) The issuer must ensure that the initial validation auditors are reasonably capable of performing an initial data validation audit according to the standards established by HHS for such audit, and must ensure that the audit is so performed.

(3) The issuer must ensure that each initial validation auditor is reasonably free of conflicts of interest, such that it is able to conduct the initial validation audit in an impartial manner and its impartiality is not reasonably open to question.

(4) The issuer must ensure validation of the accuracy of risk adjustment data for a sample of enrollees selected by HHS. The issuer must ensure that the initial validation audit findings are submitted to HHS in a manner and timeframe specified by HHS.

(c) *Second validation audit.* HHS will select a subsample of the risk adjustment data validated by the initial validation audit for a second validation audit. The issuer must comply with, and must ensure the initial validation auditor complies with, standards for such audit established by HHS, and must cooperate with, and must ensure that the initial validation auditor cooperates with, HHS and the second validation auditor in connection with such audit.

(d) *Data validation appeals.* An issuer may appeal the findings of a second